

# STATE OF COLORADO

## COLORADO DEPARTMENT OF HEALTH

*Dedicated to protecting and improving the health and environment of the people of Colorado*

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Executive Director

October 13, 1993

Mr. Richard Schassburger  
U.S. Department of Energy  
Rocky Flats Plant, Building 116  
P.O. Box 928  
Golden, Colorado 80402-0928

**RE: DOE Proposed Methodology for Statistical Comparison of Remedial Investigation Data to Background Data at the Rocky Flats Plant**

Dear Mr. Schassburger,

The Colorado Department of Health, Hazardous Materials and Waste Management Division (the Division) has reviewed the "Strawman" proposed for background comparison submitted to us on September 28, 1993. This document includes an implementation plan for Dr. Gilbert's recommendations on comparing environmental data to background data at Rocky Flats Plant. The Division accepts the proposed methodology and agrees to its implementation at Operable Units (OUs) 3 through 14. As implementation begins, DOE needs to incorporate these comments into a finalized background comparison "guidance document".

The majority of the modifications and clarifications were discussed and agreed to by DOE, EPA and CDH at the September 29 meeting and include

- Clarification of data groupings for statistical testing,
- Clear statement of the test hypothesis,
- Discussion of Detection Limits,
- Availability of informal data analysis to the Agencies,
- Effective graphical presentation of data,
- Modification of methodology for box plots, histograms, and slippage test,
- Clarification of application of hot measurement test, and
- Acceptable criteria to apply as professional judgement.

In addition, after further review, the Division is requiring several modifications and clarifications to the methodology that were not explicitly discussed or agreed to at the meeting. These modifications are itemized below and detailed in the attached comments

- Need to Develop a Formal Guidance Document,
- Modification of Document Title,
- Clarification of Statistician Involvement in Process,
- Removal of References to DOE Subcontractors from the Document,
- Need for Data Validation prior to Formal Data Presentation and Statistical Testing,
- Modification of Reference to OU 1 in Footnote 2.

Comparisons to background for the OU-1 Phase III RFI/RI Report and OU 2 Phase II RFI/RI Report will be conducted per the compromise agreement outlined in EPA's May 20, 1993 letter to DOE (Ref. 8HWM-FF).

**ADMIN RECORD**

**DOCUMENT CLASSIFICATION  
REVIEW WAIVER PER  
CLASSIFICATION OFFICE**

11/10/93

If you have any questions or would like clarification regarding these comments please contact Jeff Swanson of my staff at 692-3416.

Sincerely

A handwritten signature in cursive script, appearing to read "Gary W. Baughman".

Gary Baughman, Chief  
Facilities Section  
Hazardous Waste Control Program

cc: Martin Hestmark, EPA  
Bruce Thatcher, DOE  
Bonney Lavelle, EPA  
Jackie Berardini, CDH-OE  
Dan Miller, AGO

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Clarification & Modifications - Comparison of Site Data to Background Data.

GENERAL MODIFICATIONS AND CLARIFICATIONS

Need to Develop Formal Guidance Document

- To minimize any potential future misunderstandings of this agreement, the Division feels that it is critical for the Agencies to develop a formal guidance/policy document institutionalizing the agreement. The Strawman document was written for the purpose of facilitating agreement among the Agencies. However, the end users of this document will be the operable unit managers and sub-contractors preparing and reviewing RFI/RI reports. The majority of these people were not involved in the development of this methodology. It is critical to the future of this agreement that final documentation of this agreement be developed to clearly and concisely guide future end users in the implementation of this methodology. This formal guidance should be completed in parallel with the implementation of the agreement.

Document Title

- The Division recommends that the title of this document be revised to more accurately reflect its content and intent, that being methodology and guidelines for the comparison of site data to background data. The Division proposes the title, "Guide for Conducting Statistical Comparisons of RFI/RI Data and Background Data at the Rocky Flats Plant," for consideration.

Statistician Involvement

- One of the central themes of Dr. Gilbert's recommendations was the need for statisticians to be involved throughout the entire process. However, statistician involvement is not discussed in the methodology. The Division requests that the role of statistician in implementation of this methodology be clarified in this document.

References to DOE subcontractors

- The Division does not believe that references to specific DOE subcontractors are appropriate in this document. The Division recommends DOE review all references to sub-contractors and, where appropriate, modify the reference to more accurately reflect DOE's role and responsibilities.

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SPECIFIC MODIFICATIONS AND CLARIFICATIONS

Determine Background and OU Target Populations

- This section outlines the steps for matching site and background populations. However, it is unclear exactly how the matching will be implemented. The Division recommends that the rationale for combining media/geology groupings for testing be detailed in this section. For example, any criteria for minimum group size necessary for statistical testing should be specified. The Division further recommends adding a table or diagram depicting the general rationale for grouping data by media and geology.
- As discussed during the September 29th meeting, and emphasized by Dr. Gilbert, it is critical to statistical hypothesis testing that the hypothesis to be tested is explicitly defined and clearly stated. The Division recommends a statement of the test and null hypothesis, in both "english" (narrative qualitative description) and statistical terms, be added to this section of the methodology so there is no misunderstanding of what is being tested. This statement should also address confidence and power requirements for the tests.

Data Collection and Validation

- The Division does not agree with the blanket statement at the beginning of this discussion, "Under current IAG schedule conditions, analytical data will not be 'validated' when the background comparisons will be made in each draft report." This claim is not substantiated by the schedules submitted by DOE in the approved OU work plans and is in direct contradiction to Dr. Gilbert's Task 5 recommendations. Dr. Gilbert states that, "These data quality evaluations are conducted prior to descriptive graphical analyses and formal statistical tests." In finalizing this methodology, the Division recommends that DOE follow Dr. Gilbert's recommendations for data validation before formal graphical presentation and statistical testing. The need for variance from this approach will be considered by the Division on an OU specific basis.
- The Division recommends DOE add a discussion of detection limits to this section of the methodology. In the past there has been confusion as to what detection limits are being reported and used (instrument detection limits vs contract limits vs reporting limits). Part of this confusion may be because detection limits have not been formally discussed. This section should state what detection limits are to be used in statistical testing and how they are determined from the RFEDS data set.

Preliminary Exploratory Data Appraisal

- The Division recommends that this discussion be moved to the Data Presentation section.
- The Division interprets this section as describing the informal data analysis conducted during RFI/RI preparation and not normally included in the formal RFI/RI report. The Division recommends adding language to indicate that this informal data analysis will be made available and reviewed with the regulators in evaluating the appropriateness of the scope of the formal RFI/RI data presentation.

Data Presentation

- The Division is concerned that the description in the data presentation section may be inadequate, particularly the discussions on graphical presentations. The Division considers effective graphical presentation to be critical to understanding and interpreting the results of background comparisons. In our September 13, 1993 comments on Dr. Gilbert's

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recommendations, the Division emphasized the importance of effective graphical presentation and requested that specific graphical techniques be developed and included in this methodology.

Currently, this section reads like a list of excuses for why DOE can not complete this task per Dr. Gilbert's recommendations. This is not acceptable to the Division. The focus of this section should be on what graphical presentations need to be done and how the results should be interpreted. If a specific graph has the potential to be misinterpreted, then DOE should concentrate on how to clarify the interpretation, not on reasons for eliminating the analysis.

The Division recommends that DOE review Phase III: Data Presentation, of Dr. Gilbert's report, and consider adding more of his discussions to this section of the methodology. As a minimum, examples of acceptable quality graphics and commentary on the appropriate use and possible misuses of each type of graphic is recommended.

Box Plots

- The Division does not agree with DOE's recommendations that box plots are applicable only when there are no non-detects. The problem of estimating percentiles for data sets with multiple non-detects was not resolved by Dr. Gilbert. The Division recommends that when a reasonably small percentage of non-detects are present, percentiles be estimated using Maximum Likelihood Estimation (MLE) techniques in constructing box plots.

Histograms

- The Division does not agree with DOE's suggestion that histograms are not useful for small or highly censored data sets, such as inorganics. As stated by Dr. Gilbert, such histograms are not likely to be useful in visually assessing whether the data sets are better modeled by a normal or lognormal distribution. However, they may still be useful to visually compare the spread, central tendency, and skewness of the two data sets to look for differences that may be important.

Hot Measurement Comparison

- The Division recommends that a discussion be added to this section of the methodology to address what to do when a UTL 99/99 can not be reasonably estimated or is unknown (ie small or highly censored background data set)

Inferential Statistical Background Comparison Component

Footnote 2

- The reference in Footnote 2 to OU 1 is not appropriate and should be removed. The inferential tests conducted at OU 1 were the result of a compromise agreement, are not precedent setting for other OUs and are not the tests being proposed in this document. However, as stated in this note, limited professional judgement as presented later in this document may be applicable

Footnote 3

- This discussion should be moved to the DQOs or statistical test definition section of the document.

Slippage Test

- The Division does not agree with the limitations DOE has placed on the application of the Slippage Test. The slippage test can be applied to data sets when the largest background point is a non-detect. If the largest background data point is a non-detect then logic must be applied

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to determine if the slippage test is applicable, but the test should not be categorically eliminated.

Professional Judgement

- The Division recommends limiting the use of professional judgement to the first three criteria; spatial distribution, temporal distribution, and pattern recognition. In addition, it is recommended that the introduction to this section include acknowledgement that in applying professional judgement, the "burden of proof" lies solely on DOE. Professional judgement will only be considered by the Division on a limited basis where well documented and defensible evidence is presented.

**FIGURES:**

Task Flow Chart

- To make the process more efficient the task of eliminating non-detected analytes should be completed prior to data presentation. The flow chart should be modified to reflect this change.

Background Comparison Methodology

- This flow chart is confusing and difficult to follow due to the many multiple and undefined branches. To minimize the potential for misunderstanding this chart must either be clarified or deleted.